



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

October 23, 2000

Michael R. Harbut, MD, MPH
22255 Greenfield Rd.
Suite 440
Southfield, MI 48075

Dear Dr. Harbut:

Your petition requesting the Food and Drug Administration to issue warning statements regarding the safety of medical devices manufactured with silicone which has been catalyzed with hexachloroplatinate, was received by this office on 10/23/00. It was assigned docket number 00P-1578/CP 1 and it was filed on 10/23/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,


Gloria Ortega
Dockets Management Branch

00P-1578

ACK 1